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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,912	09/24/2003	Stephane Follonier		6522

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EXAMINER	
YANG, NELSON C	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,912	FOLLONIER ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *34-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *34-54* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-33, drawn to a system comprising a measuring cell, classified in class 435, subclass 283.1.

II. Claims 34-54, drawn to a method for detecting a target in a sample, classified in class 435, subclass 4.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the system of group I can be used to measure the refractive index or light transmission of a liquid.

4. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Stephane Follonier on March 10, 2006 a provisional election was made without traverse to prosecute the invention of group I, claims 1-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 34-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 5, 9, 10, 27, 30, 31, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 5, 27, recite the limitation "the material" in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

11. Claims 9, 10, 30, 31, recite the limitation "the at least one capture agent" in the claim. There is insufficient antecedent basis for this limitation in the claim. It is currently interpreted that "the at least one capture agent" refers to the at least one binding agent recited in claim 1.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for

patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-4, 6, 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Kumar et al [US 5,624,850].

With respect to claim 1, Kumar et al teach capillary containers where at least one region of the inner surface will be coated with a capture binding member (column 3, lines 35-45). Samples are introduced in to the capillary, along with a labeled conjugate, (column 45-56) via capillary force or active pumping (column 8, lines 27-36), and unbound conjugates are then removed from the capillary (column 8, liens 57-67).

14. With respect to claim 2, the samples are liquid samples (column 5, lines 60-67).

15. With respect to claims 3-4, the samples can be taken up in the capillary via capillary force (column 8, lines 45-56). It should also be noted that claims 3-4 refer to an intended use of the capillary. Since the capillary of Kumar is capable of capillary action, it meets the claim.

16. With respect to claim 6, Kumar et al teach that the inner surface will be coated with a capture binding member (column 3, lines 35-45), which can be the organic or inorganic layer.

17. With respect to claims 9-10, Kumar et al teach that the capture binding agent can bind directly or indirectly through an intermediate binding agent (interstitial layer) (column 3, lines 35-45)

18. With respect to claim 11, Kumar et al teach coating the capillary surface with a blocking solution to prevent non-specific adsorption (column 5, lines 24-40).

19. Claims 1, 2, 5-10, 12-15, 20, 21, 24, 27-31, 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Lockhart [US 6,974,673].

With respect to claim 1, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (light connecting element) of the waveguide

20. With respect to claim 2, a fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1).

21. With respect to claim 5, Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

22. With respect to claim 6, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27), which would be an organic coating.

23. With respect to claims 7, 8, Lockhart teaches a fiber surrounded by cladding (column 5, lines 6-25).

24. With respect to claim 9, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27).

25. With respect to claim 10, Lockhart teaches that the first biomolecular constituent can be indirectly attached to the waveguide via a linker (interstitial layer) (column 9, lines 27-55).

26. With respect to claim 12, Lockhart teaches that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

27. With respect to claim 13, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

28. With respect to claim 14, 15, Lockhart teaches light from a source such as a laser (column 4, lines 25-30), which could be considered an array of a single laser.

29. With respect to claim 18, Lockhart further teaches light-input ends (primary light connecting element) (column 4, lines 25-30), and light-output ends (secondary light connecting

element) (column 4, lines 25-45). The light-input end and the light-output end could therefore be considered to be optical windows.

30. With respect to claim 19, the ports through which fluid enters are located along the same fiber as the light-input ends and light output ends (fig. 1).

31. With respect to claim 20, Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45).

32. With respect to claim 21, fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (fluid dispensing element) (column 4, lines 20-25, fig. 1).

33. With respect to claim 22, Lockhart further teaches a sample container (column 7, lines 55-58).

34. With respect to claim 24, a fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1).

35. With respect to claim 27, Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

36. With respect to claim 28, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27), which would be an organic coating.

37. With respect to claim 29, Lockhart teaches a fiber surrounded by cladding (column 5, lines 6-25).

38. With respect to claim 30, Lockhart et al each that the first biomolecular constituent can be directly attached to the waveguide (column 9, lines 20-27).

39. With respect to claim 31, Lockhart teaches that the first biomolecular constituent can be indirectly attached to the waveguide via a linker (interstitial layer) (column 9, lines 27-55).

40. With respect to claim 33, Lockhart teaches that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56).

41. Claims 3, 4, 25, 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Lockhart [US 6,974,673] in light of Kumar et al [US 5,624,850].

With respect to claims 3, 4, 25, 26, Lockhart teaches a hollow waveguide that is a glass capillary. Although Lockhart does not teach that the capillary is capable of capillary action, one of ordinary skill would know that capillary fibers are capable of capillary action, as evidenced by Kumar et al, who teach that the samples may be taken up in a capillary via capillary force (column 8, lines 45-56). It should also be noted that claims 3-4, 25, 26, refer to an intended use of the capillary. Since the capillary of Lockhart is capable of capillary action, it meets the claim.

Claim Rejections - 35 USC § 103

42. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

43. Claims 11, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart [US 6,974,673] in view of Kumar et al [US 5,624,850].

With respect to claims, 11, 32, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart does not teach coating the waveguide with an additional layer that prevents or retards non-specific adsorption or binding of the target and/or other components of the sample.

Kumar et al, however, do teach coating the capillary surface with a blocking solution to prevent non-specific adsorption (column 5, lines 24-40). Kumar et al further teach that non-

specific adsorption as it may result in nonspecific binding of the label to the surface (column 5, lines 24-35), which would increase background noise.

Therefore, it would have been obvious to one of ordinary skill in the art to coat the capillary surface of Lockhart with a blocking solution to prevent non-specific adsorption, as suggested by Kumar et al, in order to prevent nonspecific binding of the label to the surface, which would increase background noise.

44. Claims 16, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart [US 6,974,673] in view of Aker et al [US 6,558,626].

With respect to claims 16-17, Lockhart teaches that light emanating from the light-output end (secondary light connecting element) is received by an array of opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart fails to teach that the opto-electric detectors can be photomultiplier tubes, cameras, or photodiodes.

Aker et al, however, do teach the use of detectors such as photomultiplier tubes (column 17, lines 16-23), and further teach that detectors such as photomultiplier tubes are sensitive and have a wide dynamic range (column 17, lines 23-31).

Therefore, it would have been obvious to one of ordinary skill in the art for the opto-electric detectors of Lockhart to be photomultiplier tubes, as suggested by Aker et al, in order to have detectors that are sensitive and that have a wide dynamic range.

45. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lockhart [US 6,974,673] in view of Saaski et al [US 6,484,594].

With respect to claim 23, Lockhart teaches a hollow optical waveguide with a light-input end and a light-output end, and a first biomolecular constituent attached to the inner wall of the hollow optical waveguide (column 2, lines 31-42). A fluid containing a target substance enters the cavity of the waveguide through a port and exits through another port (column 4, lines 20-25, fig. 1). Lockhart further teaches light from a source such as a laser is introduced into the light-input ends (primary light connecting element) of the waveguide (column 4, lines 25-30), and light emanating from the light-output end (secondary light connecting element) is received by opto-electric detectors (column 4, lines 25-45), such that if biomolecular constituents in fluid delivered to the waveguide (fluid dispensing element) (column 4, lines 20-25) bind to the constituents on the surface of the waveguide, a change occurs in the light propagating through the waveguide (column 4, lines 40-56). Lockhart fails to teach a disposal reservoir.

Saaski et al, however, do teach the use of a waste container (column 30, lines 40-45). Saaski et al further teach that clearing of any old, historical target material is important in any situation where it is desired that the detection apparatus detect target material that is currently entering the invention, rather than target material that has entered it in the past (column 30, lines 43-65).

Therefore, it would have been obvious to one of ordinary skill in the art to have a waste container (disposal reservoir) in the invention of Lockhart and that the fluid exiting the waveguide of Lockhart go to a waste container rather than be recirculated, as suggested by Saaski et al, in order to clear the waveguide of old, historical target material, such that the

detection apparatus detects target material currently entering the waveguide rather than target material that has entered it in the past.

Conclusion

46. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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